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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/809,140 | 03/25/2004 | Hassan Chaouk | BioCure 260 | 7389 |

44260 7590 11/29/2005

LAW OFFICE OF COLLEN A. BEARD, LLC
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| EXAMINER |
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DANIELS, MATTHEW J

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| ART UNIT | PAPER NUMBER |
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1732

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/809,140

Applicant(s)

CHAOUK ET AL.

Examiner

Matthew J. Daniels

Art Unit

1732

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 November 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See the enclosed response.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 16 November 2005 have been fully considered but they are not persuasive. The arguments appear to be on the grounds that:

- a) Sawhney teaches away from premature formation of the hydrogel, meaning formation of the hydrogel before it is at the body cavity or void.
- b) all of the embodiments are used to deliver a hydrogel without premature crosslinking.
- c) The Examiner's assertion that it would have obviously had string-like characteristics is baseless.

These arguments are not persuasive for the following reasons:

a, b, c) At issue in this case is the state of the hydrogel as it emerged from the device of Sawhney. The Applicant asserts that Sawhney's teaching to avoid premature crosslinking teaches away from the combination with Tanabe in which crosslinking occurs and a string extruded. The Examiner instead submits that Sawhney's teaching of partially gelling of the substance before being deposited in the body (10:4-8) indicates that crosslinking does occur. Moreover, Sawhney explicitly teaches that the crosslinking begins in the mixing chamber by teaching that "the prepolymer solutions begin crosslinking in chamber 46, with the resulting partially-formed gel being extruded through outlet ports 47 into the lumen or void." Furthermore, the Examiner submits that Sawhney's partially formed gel and extruded gel inherently or obviously had some shape, and thus there is no teaching away from the combination.

In this respect, the Applicant submits the definition of “extrude” is “to force, press, or push out” and submits that a glob of partially formed gel could have a number of shapes, or no shape at all. The Examiner respectfully disagrees. For completeness, the Examiner also cites the second definition of “extrude” from Merriam-Webster’s Dictionary (See the enclosed PTO-892 and reference) which states the verb also means “to shape (as metal or plastic) by forcing through a die” (emphasis added). Additionally, the Examiner cites the textbook “Materials Science and Engineering” by William D. Callister which states that “Extrusion” is “A forming technique whereby material is forced, by compression, through a die orifice.” (emphasis added).

The Applicant’s arguments appear to indicate that Sawhney’s extruded partially formed gel could have any shape, or no shape at all. However, the Examiner believes that the Applicant’s interpretation is more consistent with words like “pump” which imply no shape by their use. Instead, the Examiner submits that use of the words “extrude” or “extrusion” explicitly or implicitly teach the ordinary artisan that a shaping or forming process takes place, and that Sawhney’s extrudate would have therefore had string-like characteristics which do not teach away from the combination with Tanabe. By Sawhney’s teaching that the prepolymer solutions begin crosslinking and the partially-formed gel is extruded through outlet ports (10:7-9), the Examiner submits that the implicit or explicit teaching is that a shape or form is imparted to the partially formed gel. Because Sawhney further teaches that the rate of introduction of the prepolymer is controlled (10:4-8), Sawhney therefore also 1) teaches that extrusion rate and amount of solidification of the crosslinked hydrogel represent result effective variables which the ordinary artisan would find it prima facie obvious to optimize, and 2) provides suggestion and motivation for incorporation with Tanabe who provides a convenient device and method in

Art Unit: 1732

which the length of the lumen can be adjusted depending on the time required for the reaction of the two liquid substances (Tanabe, 14:16-18).

The Examiner therefore submits that Sawhney does not teach away from the combination with Tanabe, that the use of "extruded" implies a shaping process, and that the Examiner's assertion is well-founded in the references and the meanings of the terms used therein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Daniels whose telephone number is (571) 272-2450. The examiner can normally be reached on Monday - Friday, 7:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on (571) 272-1196. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MJD 11/21/05



MICHAEL P. COLAIANNI
SUPERVISORY PATENT EXAMINER